REMARKS

This amendment and response accompanies a Request for Continued Examination.

Claims 38-52 are pending in the present application. Claims 53-58 have been added. Claims 53-58 are directed to methods for promoting neurite outgrowth in a patient and in cell culture. Support for claims 53-58 can be found in the specification, for example, on pages 27-30.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 38-52 remain rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because practice of the claimed invention allegedly would entail undue experimentation. Applicants respectfully traverse because there is no evidence of record so much as suggesting that those skilled in the art would be unable to practice the claimed invention.

In the response mailed August 11, 2004, Applicants cited two references demonstrating the effectiveness of EPO as a neuroprotective agent. Contrary to the allegations in the Advisory Action dated September 10, 2004, Applicants did not assert that these references teach or disclose the claimed methods of treating a patient having a condition mediated by neurotoxicity, neurodegeneration, or neurological damage by administering a therapeutically effective amount of a peptide comprising one or more monomeric peptides. Rather, Applicants provided the references to demonstrate the nexus between EPO and the treatment of conditions mediated by neurotoxicity, neurodegeneration, or neurological damage.

As acknowledged by the Examiner, the present application provides evidence that the EPO mimetics represented by SEQ ID NOS. 8, 19, 20, 21 and 17 stimulate neurite outgrowth in cell culture. The Action provides no reason to believe that the skilled practitioner, after reading the present application, and in particular, the data demonstrating that the disclosed EPO mimetics stimulate neurite outgrowth, would have any trouble (1) believing that the EPO mimetics, like EPO, possess neuroprotective activity and (2) adapting protocols used for treatment with EPO for use with the EPO mimetics. As provided on page 23 of the Genc reference (Genc *et al., Brain Research,* 2000 19-31), multiple models of nervous system

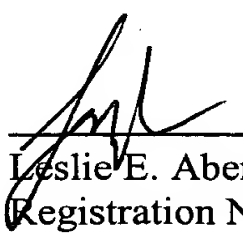
injury in animals have been used in combination with EPO. These models could easily and routinely be adapted for use with the disclosed EPO mimetics.

With regard to the alleged absence of data or evidence establishing the successful use of the claimed methods in the treatment of a patient having a condition mediated by neurotoxicity, neurodegeneration, or neurological damage, there is no requirement that Applicants engage in clinical testing before filing their application. *In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995) (because pharmaceutical inventions usually require further research and development, incentive to fully research and develop vital drugs and potential cures would be completely removed were such inventions not patentable long before being optimized or ready for human use). In fact, it is well-established that an applicant need not include any working examples demonstrating a claimed invention. *In re Fouche*, 169 U.S.P.Q. 429, 434 (C.C.P.A. 1971).

Accordingly, Applicant submit that the present specification, in combination with the high level of skill in the art in the area of erythropoietin therapy, provides ample support and enablement for the claimed methods and respectfully requests that the rejection of claims 38-52 under 35 U.S.C. § 112, first paragraph be withdrawn.

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicant submits that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

Date: May 24, 2005



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